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10/521,126

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EXAMINER

PALENIK, JEFFREY T

ART UNIT

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                             |  |
|------------------------------|------------------------|-----------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b>         |  |
|                              | 10/521,126             | HISSINK, CATHARINA EVERDINA |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>             |  |
|                              | Jeffrey T. Palenik     | 1615                        |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 27 is/are rejected.
- 7) ☒ Claim(s) 1 and 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>18 April 2005</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Remarks***

The Examiner thanks Applicants for the timely reply filed 7 January 2008, in the matter of 10/521,126.

Applicant's elections **without traverse** of Group I, claims 1-17 and 27, and of the implant species, in the reply filed on 7 January 2008 are both acknowledged.

The remaining claims of Group II (18-25, 28 and 30) and Group III (26 and 29) are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

The remaining claims 1-17 and 27 are presented and represent all claims under consideration.

### ***Information Disclosure Statement***

An Information Disclosure Statement (IDS), filed 18 April 2005, is acknowledged and has been reviewed.

### ***Specification***

The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

### ***Claim Objections***

Claims 1 and 15 are objected to because of the following informalities: they recite variables (e.g.  $T_g$ ,  $T_m$ , and  $M_n$ ), which are not expressly defined in the claims. Based on the claims of copending application 10/586,226, the above variables are understood by the Examiner to mean: glass transition temperature, melting point temperature and average molecular weight, respectively.

Appropriate correction is required.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17 and 27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24, 32, 33 and 35 of copending Application No. 10/586,226. Although the conflicting claims are not identical, they are not

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patentably distinct from each other because the claims of both applications are directed obvious variants of one another reciting biodegradable phase-separated multiblock copolymers which are connected by way of aliphatic chain-extendors. Both applications recite similar Markush groups of cyclic and non-cyclic monomers for constructing the pre-polymers. More particularly, instant claim 27 and conflicting claim 32 both recite implant device applications which comprise the multiblock copolymer composition, which is recited in claim 1 of both applications. An artisan of ordinary skill in the pharmaceutical art would be able to practice the instant invention with a reasonable expectation of success under the guidance of the '226 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 11 and 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 3, the phrase "optionally" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(h).

Claim 8 recites the limitation "said non-cyclic monomers" in lines 2-3 of the claim. There is presently insufficient antecedent basis for this limitation in the claim. However, it is

observed by the Examiner that were claim 8 to refer to claim 6 rather than claim 5, then no lack of antecedent basis would exist. Therefore, for the purposes of examination on the merits, the Examiner will prosecute claim 8 as though it were dependent from claim 6.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 11 recites the broad recitation wherein PEG has "a molecular weight of 150-4000", and the claim also recites that PEG has "a molecular weight of preferably of 150-2000, more preferably 300-1000" which are the narrower statements of the range/limitation. For the purposes of examination on the merits, the Examiner broadly and reasonable interprets the limitations to the instant claim as reciting PEG having a molecular weight of 150-4000.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP §

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2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 15 recites the broad recitation wherein pre-polymer (B) has an average molecular weight ( $M_n$ ) of larger than 1000, and the claim also recites average molecular weight ranges of preferably larger than 2000 and more preferably larger than 3000, which are the narrower statements of the range/limitation. For the purposes of examination on the merits, the Examiner broadly and reasonable interprets the limitations to the instant claim as reciting pre-polymer (B) having an average molecular weight of larger than 1000.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required

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feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 16 recites the broad recitation wherein the content of pre-polymer (B) is 10-90 wt.%, and the claim also recites a preferred wt.% range of 30-50%, which is the narrower statement of the range/limitation. For the purposes of examination on the merits, the Examiner broadly and reasonable interprets the limitations to the instant claim as reciting the content of pre-polymer (B) as ranging from 10-90 wt.%.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 17 recites the broad recitation wherein the copolymer composition of claim 1 has an intrinsic viscosity of at least 0.1 dl/g, and the claim also recites a preferred range of 1-4 dl/g, which is the narrower statement of the range/limitation. For the purposes of examination on the merits, the Examiner broadly and



reasonable interprets the limitations to the instant claim as reciting the composition of claim 1 having an intrinsic viscosity of at least 0.1 dl/g.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 and 12-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Penco et al. (*Macromolecular Chemistry and Physics*).

The instant claims are directed to a biodegradable multiblock copolymer comprising two pre-polymer components (A) and (B), which are linked by a multifunctional chain-extender (claims 1, 10 and 12). Pre-polymer (A) has glass transition temperature ( $T_g$ ) is less than 37°C, and pre-polymer (B) has a melting point temperature ( $T_m$ ) between 40-100°C. Claims 10 and 12 both further limit claim 1 such that they recite how to obtain pre-polymers (A) and (B), respectively. However, the aforementioned limitations are product-by-process limitations and, per MPEP 2113, hold no patentable weight. The chain-extender is recited as an aliphatic polyether (claims 2 and 9). Pre-polymer (A) is further limited to comprising ester groups such as diols, dicarboxylic acids and hydrocarboxylic acids as well as other cyclic and/or non-cyclic monomers, and/or carbonate groups (claims 3 and 5-8). Claim 4 limits the composition of claim 1 to further comprising a polyether pre-polymer. Pre-polymer (B) is limited to poly- $\epsilon$ -caprolactone (claims 13 and 14), wherein it is further limited by its average molecular weight

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(claim 15) and its percent weight representation within the composition (claim 16). Claim 17 recites intrinsic viscosity limitations to the composition of claim 1.

Penco et al. teach multi-block copolymers having the structure of poly(ester-carbonate)s obtained via chain extension involving poly(lactic-glycolic acid) oligomers (PLGA) and oligomeric poly( $\epsilon$ -caprolactone)s or PCDTs (Abstract). Chain extension of the PLGA-PCDT multi-block copolymer compounds is taught through the additional inclusion of poly(ethylene glycol) or PEG oligomers (§2 *Introduction*). Tables 1 and 4 both teach molecular characterizations for PLGA-PCDT block copolymers, and more specifically the following compounds: PLGA 50/50-PCDT1250 and PLGA 50/50-PCDT2000, as shown below:

| Molecular Characteristics:  | PLGA-PCDT Block Copolymers |                       |
|---|----------------------------|-----------------------|
| Table 1 Parameter   | PLGA 50/50-PCDT1250        | PLGA 50/50-PCDT2000   |
| Intrinsic Viscosity $[\eta]$ (dl/g)<br>Claimed: $[\eta]$ = at least 0.1 dl/g  | 1.20 dl/g                  | 0.82 dl/g             |
| Table 3 Parameters  |                            |                       |
| PCDT in wt. %<br>Claimed: %-wt. = 10-90%                                      | 39.31 %                    | 50.89 %               |
| Glass Transition Temp. ( $T_g$ )<br>Claimed: ( $T_g$ ) is $<37^\circ\text{C}$ | $-57.9^\circ\text{C}$      | $-45.3^\circ\text{C}$ |
| Melting Point Temp. ( $T_m$ )<br>Claimed: ( $T_m$ ) is $40-100^\circ\text{C}$ | $40.3^\circ\text{C}$       | $49.4^\circ\text{C}$  |

The pre-polymer (B), represented by the PCDT component, in both examples is greater than 1000 (e.g. PCDT1250 and PCDT2000).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-17 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Penco et al (*Macromolecular Chemistry and Physics*) in view of Cohn et al. (US Pre-Grant Publication 2001/0009662).

The instant claims are directed to a biodegradable multiblock copolymer comprising two pre-polymer components (A) and (B), which are linked by a multifunctional chain-extender, as described above. The composition is further limited wherein the aliphatic chain-extender is polyethylene glycol (PEG) having a molecular weight ranging from 150-4000, also as discussed above. Independent claim 27 recites an implant device comprising a copolymer of claim 1.

The teachings of Penco et al. are discussed above.

Penco neither expressly teaches the use of any particular weight of PEG or incorporation of the copolymer composition into a medical delivery device such as an implant.

Cohn et al. teaches a polymeric composition comprising coupled AB diblocks, where A is a polyester unit derived from the polymerization of compounds such as lactic acid, lactide, glycolic acid, glycolide,  $\epsilon$ -caprolactone,  $\delta$ -valerolactone, trimethylene carbonate and p-dioxanone and B is derived from a compound such as a hydroxyl-terminated compound initiating the polymerization of said monomers from said polyester unit (e.g.  $\epsilon$ -caprolactone). Said AB diblock being further reacted with one or more coupling or crosslinking agents to form di-diblocks or multi-block polymers (claim 1). Polyethylene glycol, also known as polyethylene oxide (PEO) and polyoxyethylene (POE), is taught as being used to extend the polymer chains of di- and tri-blocks of the invention (see ¶[0092]). Example 3 teaches the synthesis of [MPEG 550-HDI]2-[(I)LA4-PPG1000-LA4], which is an ACA tri-block of lactic acid (LA)-polypropylene glycol 1000 (PPG1000)-LA where the tri-block chain is extended using polyethylene glycol methyl ether having a molecular weight of 550. The product is characterized as having a glass transition temperature around -44°C, having two melting temperatures (e.g. endotherms) at 11°C and 34°C, and a viscosity value of 43,000 centipoise (cps) at 27°C. Pre-polymer (B), which in the case of Example 3 is the PPG1000 component, was added in the amount of 40 grams and represents approximately 24.5% of the entire composition produced by the Example. Example 8 teaches synthesis of another tri-block polymer which uses poly-caprolactone having a molecular weight of 1250. The polymers of the present invention are

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also taught as being used in various forms, structures such as films, rods, cylinders, gels and biodegradable articles, among many others, which have medical uses such as preventing tissue-to-tissue or tissue-to-device adhesion (see ¶¶[0093] and [0094]).

Cohn et al. does not expressly teach pre-polymer melting point temperatures ranging as instantly claimed. Intrinsic viscosity is also not taught as being used to characterize any of the practiced multi-block copolymer products.

In view of the combined teachings of the prior art, one of ordinary skill in the pharmaceutical art would have been motivated to react the instantly claimed cyclic and/or non-cyclic monomer precursors in combination with the aliphatic polyether chain extending polymers with a reasonable expectation of successfully achieving the claimed biodegradable multiblock copolymer formulation of the instant invention. Such would have been obvious in the absence of evidence to the contrary since both Penco et al. and Cohn et al. teach overlapping components and variations to their respective compositions, which can be incorporated into the instant composition as well as the instant method for closing wounds and preventing microbial growth. Though the compositions practiced by Penco et al. are not expressly taught as being implemented into an implant device, Penco does provide a broad teaching stating that all the products synthesized show similar or lower degradation rates compared to typical samples of PLGA normally used as components with drug delivery systems (see *Conclusion* “4”) thereby providing motivation for an artisan of ordinary skill to implement the practiced invention into implantable and biodegradable medical devices such as those taught by Cohn et al. (see ¶[0093]).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

All claims have been rejected; no claims are allowed.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/  
Examiner, Art Unit 1615

/MP WOODWARD/  
Supervisory Patent Examiner, Art Unit 1615